IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

LINDA L. KITZMILLER and
RICHARD C. KITZMILLER, her husband,

Plaintiffs,

v. Case No 2:05-CV-22

JEFFERSON SUPPLY COMPANY,

Defendant.

REPORT AND RECOMMENDATION/OPINION

Procedural History

On October 25, 2004, Plaintiffs Linda L. Kitzmiller and Richard C. Kitzmiller ("Plaintiffs") filed a Complaint in the Circuit Court of Grant County, West Virginia, against The Board of Education of Grant County, West Virginia, and The Jefferson Supply Company ("Jefferson"). On January 19, 2005, Plaintiffs filed an Amended Complaint solely against Jefferson. Jefferson removed this matter to the United States District Court for the Northern District of West Virginia. On March 8, 2005, Jefferson filed its Answer to the Amended Complaint and Third-Party Complaint against The Butcher Company ("Butcher"). On September 30, 2005, Butcher filed its "Third-Party Counterclaim Against Third-Party Plaintiff The Jefferson Supply Company" [Docket Entry 61]. On March 2, 2006, Plaintiffs and Butcher filed their "Joint Motion to Dismiss Count II" and " Joint Motion to Dismiss the Butcher Company" [Docket Entries 101 and 102]. On April 10, 2006, the undersigned United States Magistrate Judge recommended the joint motions to dismiss be granted. On June 8, 2006, United States District Judge Robert E. Maxwell adopted the Report and

Recommendation, granting the joint motions to dismiss Butcher and Count II, both with prejudice [Docket Entry 157].

On June 22, 2006, Jefferson filed its "Motion for Summary Judgment" and Memorandum in support thereof [Docket Entry 163]. Plaintiffs filed their Response to Jefferson's Motion for Summary Judgment on July 14, 2006 [Docket Entry186]. Jefferson filed its Reply on July 28, 2006 [Docket Entry 193].

Prior to the September 29, 2006 hearing on the Motion for Summary Judgment, Plaintiff filed Motion to Exclude Testimony of Samuel Spagnolo, M.D. (Docket Entry 202); Defendant filed its Motion To Exclude Opinion Testimony of Dr. Richard Catlett on Issues of Causation (Docket Entry 204); Defendant filed itsDaubert Motion to Exclude the Testimony of Dr. Dominic Gaziano (Docket Entry 205); Defendant filed its Daubert Motion to Exclude the Testimony of Stephen E. Petty, P.E., C. I. H. (Docket Entry 206; Defendant filed its Daubert Motion to Exclude Opinion Testimony of Dr. Allan Kunkel on Issue of Causation (Docket Entry 207) and Plaintiff filed Motion to Exclude Testimony of Michael J. Wernke (Docket Entry 211).

The various motions to exclude testimony, Daubert and otherwise designated, were set for evidentiary hearings and arguments on various commencing with October 30, 2006 and ending on December 14, 2006.

These matters are before the undersigned United States Magistrate Judge for a Report and Recommendation to the District Judge pursuant to an Order of Referral entered September 19, 2005.

SUMMARY JUDGMENT

The parties appeared before the undersigned for hearing on Jefferson's Motion for Summary Judgment on September 29, 2006. Plaintiffs appeared in person and by counsel, Guy Bucci and

Nelson Michael. Defendant was present by counsel, Debra Herron and Michael Crim.

I. Relevant Facts

Plaintiff Linda Kitzmiller began working as a custodian for the Grant County Board of Education in 2000 as a substitute custodian. (See Defendant's Exhibit A, p. 51). On or about August, 2001, Plaintiff began working half-time at Petersburg High School and maintained that position until approximately November, 2001, when she was transferred to Maysville Elementary School. (See id. at 47). Plaintiffs allege that pursuant to her duties, Plaintiff Kitzmiller used and was exposed to two specific products, Bath Mate and Blue Skies, and allege these products were distributed to the Board of Education by Defendant Jefferson. Plaintiff has been diagnosed with Bronchiolitis Obliterans Organizing Pneumonia ("BOOP") and Plaintiffs allege that Defendant Jefferson is responsible for said condition.

II. The Parties' Contentions

Jefferson contends it is entitled to summary judgment because: 1) Jefferson has no duty to Plaintiffs and 2) Plaintiffs are unable to establish causation.

Plaintiffs contend Jefferson is not entitled to summary judgment because it assumed the Board of Education's duty to Plaintiffs and 2) they have at least established a jury question as to causation.

III. Discussion

A. Standard for Summary Judgment

Summary judgment is appropriate "if there is no genuine issue of material fact. Charbonnages de France v. Smith, 597 F.2d 406 (4th Cir. 1979). An issue is genuine "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." Anderson

v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The party seeking summary judgment has the initial burden to show absence of evidence to support the nonmoving party's case. Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). This burden does not require the moving party to show evidence that proves absence of a genuine issue of material fact, but only to point out its absence. Id.

The burden then shifts to the party opposing the motion. The adverse party may not rest upon mere allegations or denials, Anderson, 477 U.S. at 248, and summary judgment is appropriate if the adverse party fails to show, under Rule 56, the existence of an element essential to that party's case. Celotex, 477 U.S. at 322. A mere scintilla of evidence supporting the case is insufficient. Anderson, 477 U.S. at 252. With regard to the burden on the adverse party, Rule 56(e) provides in part that:

> [W]hen a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleadings, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party.

However, in evaluating a motion for summary judgment, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson, supra at 255. With these standards in mind, the Court will proceed to the defendants' motion.

B. Duty

Jefferson first argues that it is entitled to summary judgment as to Counts I and III because Jefferson owed no duty to Plaintiffs. Plaintiffs argue that Jefferson's duty is established as a matter of law because: 1) the Board of Education entered into an agreement with Jefferson to distribute and

install dispensers and chemical cleaning products and to train its personnel on their safe use; 2) there is evidence to show that Jefferson was expected to and indeed did perform training and safe use functions requested by the Board of Education; and 3) Plaintiffs' expert industrial hygienist (Stephen E. Petty) testified and reported that the information and training provided by Jefferson was insufficient and not effective.

20 C.F.R. §1910.1200 provides as follows, in pertinent part:

> (a) Purpose.
>
> (1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training.
>
> (2) This occupational safety and health standard is intended to address comprehensively the issue of evaluating the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, and to preempt any legal requirements of a state, or political subdivision of a state, pertaining to this subject. Evaluating the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, may include, for example, but is not limited to, provisions for: developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of material safety data sheets to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures. Under section 18 of the Act, no state or political subdivision of a state may adopt or enforce, through any court or agency, any requirement relating to the issue addressed by this Federal standard, except pursuant to a Federally-approved state plan.
>
> (b) Scope and application.
>
> (1) This section requires chemical manufacturers or importers to assess the hazards of chemicals which they produce or import, and all employers to provide information to their employees about the hazardous chemicals to which they are exposed, by

means of a hazard communication program, labels and other forms of warning, material safety data sheets, and information and training. In addition, this section requires distributors to transmit the required information to employers. (Employers who do not produce or import chemicals need only focus on those parts of this rule that deal with establishing a workplace program and communicating information to their workers. Appendix E of this section is a general guide for such employers to help them determine their compliance obligations under the rule.)

(2) This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

. . . .

(c) Definitions.

. . . .

Chemical means any element, chemical compound or mixture of elements and/or compounds.

Chemical manufacturer means an employer with a workplace where chemical(s) are produced for use or distribution.

Chemical name means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature, or a name which will clearly identify the chemical for the purpose of conducting a hazard evaluation.

. . . .

Distributor means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers.

Employee means a worker who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Workers such as office workers or bank tellers who encounter hazardous chemicals only in non-routine, isolated instances are not covered.

Employer means a person engaged in a business where chemicals are either used, distributed, or are produced for use or distribution, including a contractor or subcontractor.

. . . .

Exposure or exposed means that an employee is subjected in the course of

employment to a chemical that is a physical or health hazard, and includes potential (e.g. accidental or possible) exposure. "Subjected" in terms of health hazards includes any route of entry (e.g. inhalation, ingestion, skin contact or absorption.)

. . . .

Hazardous chemical means any chemical which is a physical hazard or a health hazard.

Hazard warning means any words, pictures, symbols, or combination thereof appearing on a label or other appropriate form of warning which convey the specific physical and health hazard(s), including target organ effects, of the chemical(s) in the container(s). (See the definitions for "physical hazard" and "health hazard" to determine the hazards which must be covered.)

Health hazard means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. Appendix A provides further definitions and explanations of the scope of health hazards covered by this section, and Appendix B describes the criteria to be used to determine whether or not a chemical is to be considered hazardous for purposes of this standard.

Identity means any chemical or common name which is indicated on the material safety data sheet (MSDS) for the chemical. The identity used shall permit cross-references to be made among the required list of hazardous chemicals, the label and the MSDS.

Immediate use means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.

. . . .

Label means any written, printed, or graphic material displayed on or affixed to containers of hazardous chemicals.

Material safety data sheet (MSDS) means written or printed material concerning a hazardous chemical which is prepared in accordance with paragraph (g) of this section.

Mixture means any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction.

. . . .

Produce means to manufacture, process, formulate, blend, extract, generate, emit, or repackage.

. . . .

Use means to package, handle, react, emit, extract, generate as a byproduct, or transfer.

. . . .

Work area means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

Workplace means an establishment, job site, or project, at one geographical location containing one or more work areas.

(d) Hazard determination.

(1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to determine if they are hazardous. Employers are not required to evaluate chemicals unless they choose not to rely on the evaluation performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

(2) Chemical manufacturers, importers or employers evaluating chemicals shall identify and consider the available scientific evidence concerning such hazards. For health hazards, evidence which is statistically significant and which is based on at least one positive study conducted in accordance with established scientific principles is considered to be sufficient to establish a hazardous effect if the results of the study meet the definitions of health hazards in this section. Appendix A shall be consulted for the scope of health hazards covered, and Appendix B shall be consulted for the criteria to be followed with respect to the completeness of the evaluation, and the data to be reported.

(3) The chemical manufacturer, importer or employer evaluating chemicals shall treat the following sources as establishing that the chemicals listed in them are hazardous:

(i) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA); or,

(ii) Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment, American Conference of Governmental Industrial Hygienists (ACGIH) (latest edition). The chemical manufacturer, importer, or employer is still responsible for evaluating the hazards associated with the chemicals in these source

lists in accordance with the requirements of this standard.

(4) Chemical manufacturers, importers and employers evaluating chemicals shall treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purposes:

(i) National Toxicology Program (NTP), Annual Report on Carcinogens (latest edition);

(ii) International Agency for Research on Cancer (IARC) Monographs (latest editions); or

(iii) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.

Note: The Registry of Toxic Effects of Chemical Substances published by the National Institute for Occupational Safety and Health indicates whether a chemical has been found by NTP or IARC to be a potential carcinogen.

. . . .

(e) Written hazard communication program.

(1) Employers shall develop, implement, and maintain at each workplace, a written hazard communication program which at least describes how the criteria specified in paragraphs (f), (g), and (h) of this section for labels and other forms of warning, material safety data sheets, and employee information and training will be met, and which also includes the following:

(i) A list of the hazardous chemicals known to be present using an identity that is referenced on the appropriate material safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas); and,

(ii) The methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas.

. . . .

(3) The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this paragraph (e).

(4) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director, in accordance with the requirements of 29 CFR 1910.1020(e).

. . . .

(f) Labels and other forms of warning.

(1) The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged or marked with the following information:

(i) Identity of the hazardous chemical(s);

(ii) Appropriate hazard warnings; and

(iii) Name and address of the chemical manufacturer, importer, or other responsible party.

. . . .

(3) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation.

(4) If the hazardous chemical is regulated by OSHA in a substance-specific health standard, the chemical manufacturer, importer, distributor or employer shall ensure that the labels or other forms of warning used are in accordance with the requirements of that standard.

(5) Except as provided in paragraphs (f)(6) and (f)(7) of this section, the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with the following information:

(i) Identity of the hazardous chemical(s) contained therein; and,

(ii) Appropriate hazard warnings, or alternatively, words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous chemical.

(6) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by

paragraph (f)(5) of this section to be on a label. The written materials shall be readily accessible to the employees in their work area throughout each work shift.

(7) The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. For purposes of this section, drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient are exempted from labeling.

(8) The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

(9) The employer shall ensure that labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

(10) The chemical manufacturer, importer, distributor or employer need not affix new labels to comply with this section if existing labels already convey the required information.

(11) Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within three months of becoming aware of the new information. Labels on containers of hazardous chemicals shipped after that time shall contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importers, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

(g) Material safety data sheets.

(1) Chemical manufacturers and importers shall obtain or develop a material safety data sheet for each hazardous chemical they produce or import. Employers shall have a material safety data sheet in the workplace for each hazardous chemical which they use.

(2) Each material safety data sheet shall be in English (although the employer may maintain copies in other languages as well), and shall contain at least the following information:

(i) The identity used on the label, and, except as provided for in paragraph (i) of this section on trade secrets:

(A) If the hazardous chemical is a single substance, its chemical and common name(s);

(B) If the hazardous chemical is a mixture which has been tested as a whole to determine its hazards, the chemical and common name(s) of the ingredients which contribute to these known hazards, and the common name(s) of the mixture itself; or,

(C) If the hazardous chemical is a mixture which has not been tested as a whole:

(1) The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise 1% or greater of the composition, except that chemicals identified as carcinogens under paragraph (d) of this section shall be listed if the concentrations are 0.1% or greater; and,

(2) The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise less than 1% (0.1% for carcinogens) of the mixture, if there is evidence that the ingredient(s) could be released from the mixture in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health risk to employees; and

(3) The chemical and common name(s) of all ingredients which have been determined to present a physical hazard when present in the mixture;

(ii) Physical and chemical characteristics of the hazardous chemical (such as vapor pressure, flash point);

(iii) The physical hazards of the hazardous chemical, including the potential for fire, explosion, and reactivity;

(iv) The health hazards of the hazardous chemical, including signs and symptoms of exposure, and any medical conditions which are generally recognized as being aggravated by exposure to the chemical;

(v) The primary route(s) of entry;

(vi) The OSHA permissible exposure limit, ACGIH Threshold Limit Value, and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the material safety data sheet, where available;

(vii) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Annual Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest editions), or by OSHA;

(viii) Any generally applicable precautions for safe handling and use which are

known to the chemical manufacturer, importer or employer preparing the material safety data sheet, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for clean-up of spills and leaks;

(ix) Any generally applicable control measures which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, such as appropriate engineering controls, work practices, or personal protective equipment;

(x) Emergency and first aid procedures;

(xi) The date of preparation of the material safety data sheet or the last change to it; and,

(xii) The name, address and telephone number of the chemical manufacturer, importer, employer or other responsible party preparing or distributing the material safety data sheet, who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

(3) If no relevant information is found for any given category on the material safety data sheet, the chemical manufacturer, importer or employer preparing the material safety data sheet shall mark it to indicate that no applicable information was found.

(4) Where complex mixtures have similar hazards and contents (i.e. the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture), the chemical manufacturer, importer or employer may prepare one material safety data sheet to apply to all of these similar mixtures.

(5) The chemical manufacturer, importer or employer preparing the material safety data sheet shall ensure that the information recorded accurately reflects the scientific evidence used in making the hazard determination. If the chemical manufacturer, importer or employer preparing the material safety data sheet becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information shall be added to the material safety data sheet within three months. If the chemical is not currently being produced or imported the chemical manufacturer or importer shall add the information to the material safety data sheet before the chemical is introduced into the workplace again.

(6)(i) Chemical manufacturers or importers shall ensure that distributors and employers are provided an appropriate material safety data sheet with their initial shipment, and with the first shipment after a material safety data sheet is updated;

(ii) The chemical manufacturer or importer shall either provide material safety data sheets with the shipped containers or send them to the distributor or employer prior to or at the time of the shipment;

(iii) If the material safety data sheet is not provided with a shipment that has been

labeled as a hazardous chemical, the distributor or employer shall obtain one from the chemical manufacturer or importer as soon as possible; and,

(iv) The chemical manufacturer or importer shall also provide distributors or employers with a material safety data sheet upon request.

(7)(i) Distributors shall ensure that material safety data sheets, and updated information, are provided to other distributors and employers with their initial shipment and with the first shipment after a material safety data sheet is updated;

(ii) The distributor shall either provide material safety data sheets with the shipped containers, or send them to the other distributor or employer prior to or at the time of the shipment;

(iii) Retail distributors selling hazardous chemicals to employers having a commercial account shall provide a material safety data sheet to such employers upon request, and shall post a sign or otherwise inform them that a material safety data sheet is available;

(iv) Wholesale distributors selling hazardous chemicals to employers over-the-counter may also provide material safety data sheets upon the request of the employer at the time of the over-the-counter purchase, and shall post a sign or otherwise inform such employers that a material safety data sheet is available;

(v) If an employer without a commercial account purchases a hazardous chemical from a retail distributor not required to have material safety data sheets on file (i.e., the retail distributor does not have commercial accounts and does not use the materials), the retail distributor shall provide the employer, upon request, with the name, address, and telephone number of the chemical manufacturer, importer, or distributor from which a material safety data sheet can be obtained;

(vi) Wholesale distributors shall also provide material safety data sheets to employers or other distributors upon request; and,

(vii) Chemical manufacturers, importers, and distributors need not provide material safety data sheets to retail distributors that have informed them that the retail distributor does not sell the product to commercial accounts or open the sealed container to use it in their own workplaces.

(8) The employer shall maintain in the workplace copies of the required material safety data sheets for each hazardous chemical, and shall ensure that they are readily accessible during each work shift to employees when they are in their work area(s). (Electronic access, microfiche, and other alternatives to maintaining paper copies of the material safety data sheets are permitted as long as no barriers to immediate employee access in each workplace are created by such options.)

(9) Where employees must travel between workplaces during a workshift, i.e., their

work is carried out at more than one geographical location, the material safety data sheets may be kept at the primary workplace facility. In this situation, the employer shall ensure that employees can immediately obtain the required information in an emergency.

(10) Material safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).

(11) Material safety data sheets shall also be made readily available, upon request, to designated representatives and to the Assistant Secretary, in accordance with the requirements of 29 CFR 1910.1020(e). The Director shall also be given access to material safety data sheets in the same manner.

(h) Employee information and training.

(1) Employers shall provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new physical or health hazard the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and material safety data sheets.

(2) Information. Employees shall be informed of:

(i) The requirements of this section;

(ii) Any operations in their work area where hazardous chemicals are present; and,

(iii) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and material safety data sheets required by this section.

(3) Training. Employee training shall include at least:

(i) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(ii) The physical and health hazards of the chemicals in the work area;

(iii) The measures employees can take to protect themselves from these hazards,

> including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,
>
> (iv) The details of the hazard communication program developed by the employer, including an explanation of the labeling system and the material safety data sheet, and how employees can obtain and use the appropriate hazard information.

Neither party disputes that §1920.1200 imposes a duty to train on employers. Nor does either party dispute that the regulation does not confer on a distributor a duty to train employees. Both parties, however, concede that the employer's duty to train its employees can be delegated by the employer to the distributor, and that the distributor, in turn, can assume that duty. Both parties also agree that Jefferson did agree to assume, at least in part, the employer's duty to train, and that the Board of Education employer did delegate, at least in part, its duty to train its employees. Both parties finally agree that Jefferson did perform training for the board's employees. The issues before this Court are therefore: 1) the extent of the delegation of duty by the Board of Education to Jefferson; 2) to what extent did Jefferson assume said duty; and 3) whether Jefferson performed its duty satisfactorily and sufficiently.

Based on the totality of the record now before the Court, there are significant factual issues with respect to what training duties the Board of Education delegated to Jefferson; what training duties Jefferson assumed from the Board of Education; and whether Jefferson provided the training to the Board of Education employees as contemplated by the parties agreement.

C. Causation

Jefferson next argues it is entitled to summary judgment as to Counts I and III because Plaintiffs are unable to establish causation. Plaintiffs, in order to prevail, must show there is at least

an issue of material fact regarding both general causation and specific causation.

Based on the recommendations hereinafter made with respect to the motion to exclude the testimony of Stephen E. Petty and the motion to exclude the testimony of Dr. Richard Catlett, if adopted by the District Court, there will be an issue of material fact with respect to the issues of general and specific causation which precludes summary judgment at this stage of the proceedings based on those issues.

For the reasons stated herein, I **RECOMMEND** Jefferson's Motion for Summary Judgment (Docket Entry 163) be **DENIED**.

DAUBERT

Standard

Under Federal Rule of Evidence 702[1], a court should admit expert testimony that is reliable and helps the jury understand the evidence. To determine reliability, a court should evaluate the expert's methodology, not his conclusion. TFWS v. Schaefer, 325 F.3d 234, 240 (4th Cir. 2003).

It is incumbent on the trial judge "faced with a proffer of expert scientific testimony [to] conduct 'a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."' Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001). The court's evaluation of the proposed expert testimony "is always a flexible one, and the court's

[1]FRE 702 provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form or an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and(3) the witness has applied the principles and methods reliably to the facts of the case."

conclusion necessarily amount to an exercise of broad discretion guided by the overarching criteria of relevance and reliability." "A reliable expert opinion must be based on scientific technical or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." Oglesby v. General Motors Corp., 190 F.3d 244, 250 (4th Cir. 1999).

The reliability of the expert is assessed using the following nonexclusive factors:

1) whether the expert's theory can be or has been tested;

2) whether the theory has withstood peer review and publication;

3) whether there is a known or potential rate of error;

4) whether standards exist for the application of the theory; and

5) whether the theory has been generally accepted by the relevant scientific community.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U. S. 579 (1993).

"If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached... The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.' The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable." Advisory Committee Note to Rule 702 (internal citations and quotations omitted).

In Westberry v. Gummi, 178 F.3d 257, 260-261 (4th Cir. 1999), the Court recognized that:

> Rule 702 was intended to liberalize the introduction of relevant expert evidence. And, the court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to being tested by "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the

burden of proof."

Generally, the burden is on the proponent of the expert testimony to establish its admissibility by a preponderance of the evidence. See Higginbotham v. KCS Int'l, Inc., 85 Fed. Appx. 911 (4th Cir. 2004).

Discussion

A.

DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF STEPHEN E. PETTY, P.E., C.I.H. (Docket Entry 206)

Defendant seeks to exclude the proposed expert testimony of Stephen E. Petty ("Mr. Petty"), a professional engineer and Certified Industrial Hygienist contending Mr. Petty:

1) "failed to apply and follow the appropriate methodology in arriving at his opinions, rendering the same unreliable."

2) "Petty's opinions as to Mrs. Kitzmiller's medical condition are proffered in an area wherein Petty is admittedly, 'not an expert' and are therefore, inherently unreliable."

3) "Petty's opinions as to improper ventilation are propounded upon inappropriate methodology and are therefore unreliable."

4) "Petty's ventilation opinions are untimely."

5) "Petty's opinions as to Jefferson's duty and subsequent failure to provide adequate training regarding hazards [sic] products are improper as the same exceed the permissible testimony of an expert and should be excluded."

Stephen E. Petty graduated from the University of Washington with honors with a degree in chemical engineering. Thereafter, he obtained a masters degree in chemical engineering. He later

completed his masters in business administration (MBA). He passed the examinations and experience requirements to become a certified industrial hygienist and has maintained his certification through required continuing education. He is presently registered as a professional engineer in West Virginia, Kentucky and Ohio.

For a period of approximately ten years, Mr. Petty worked for Battel, a non-profit corporation designing and setting up laboratories relative to the testing of heating and ventilation systems and drafting standards relating to toxicity exposure. Mr. Petty then worked for Columbia Gas for a period of ten years, during which he registered nine patents in his name. In 1996, he started his own consulting company, which he continues to own and operate. His company had done studies and given testimony in hundreds of mold cases. Mr. Petty readily admits his testimony in mold cases is not specifically relevant to the issues in the Kitzmiller case, but maintains that the methodology used in evaluating those cases is relevant to Kitsmilller.

He was retained by Ohio to examine and review the HVAC systems in all of its public school buildings, old and new, and prepare and present reports.

He was retained by Allegheny Ballistic Lab to investigate, study and report on why people scanning Iraqi documents suffered with skin rashes. He sampled documents for molds and prepared opinion reports on cause and effect.

He was also retained by the Columbus Blue Jackets to examine their twenty-room complex, conduct interviews and analysis to determine why the players were becoming ill from being in the locker room portion of the complex. From his study, he was able to determine that the air handling system over the locker room area had been shut down to eliminate chill on players. That allowed contaminants to build up. Additionally, the air intake pipe was located near a smoking area and was

bringing smoke contaminants into the locker room area.

Mr. Petty was retained by Plaintiff as a general causation expert. He first looked at the MSDS's to see if any compounds listed would cause symptoms like those experienced by Plaintiff.

Mr. Petty took the experience he had gained over the prior thirty years, his education, and his familiarity with other disciplines and applied them to analyzing the issue of exposure in Plaintiff's case. He relied on Plaintiff's statement, an Italian case report, nine other documents (including limited MSDS's, photos of the command dispensing center, pictures of the closets in the school, the complaint filed in the action)[2], the medical diagnosis of so-called BOOP, and his knowledge that Ms. Kitzmiller worked as a janitor in an elementary school using cleaning chemicals in the preparation of his June 24, 2005, report. He developed a worker's activity time line for Ms. Kitzmiller and descriptions of work spaces where the products were stored and dispensed [3] related to the use of various cleaning chemicals at the school. He focused on the spray mechanism and ventilation in the area of use. He reviewed the available MSDSs and concluded that "both The Blue Skies Disinfectant Cleaner and Bath Mate Acid Free Disinfectant contain an alkyl-dimethyl-benzyl-ammonium chloride associated with this case of BOOP. None of the other two MSDSs for BathMate Acide Free Washroom Cleaner or Speedball 2000 Heavy Duty Spray Cleaner contains this chemical."[4] He believed the spraying mechanism or some form of aerosolization was the most likely vehicle of exposure because her symptoms were all lung related suggesting inhalation. In order to confirm or debunk his preliminary theory, he needed more information, such as Plaintiff's

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[2]Plaintiff's Trial Exhibit 233, Daubert Exhibit 14, p. 1044.

[3]Plaintiff's Trial Exhibit 234-5, Daubert Exhibit 14, pp. 1045-6.

[4]Plaintiff's Trial Exhibit 337, Daubert Exhibit 14, p. 1048.

hobbies, home activities and other MSDS's.

Mr. Petty admits he is not a physician and, therefore, not qualified to offer specific causation opinions. He does, however, maintain that he is qualified to offer general causation opinions.

After he issued his June 24, 2005, report, he reviewed depositions taken in this case as they related to the activities of Plaintiff and the ventilation at the school where she worked and used cleaning supplies. He reviewed Ms. Kitzmiller's prior work history beginning in 1994 and found no suspect chemicals. He also reviewed the training provided related to Butcher's products supplied by Jefferson. He calculated the room sizes and times spent in the rooms by Ms. Kitzmiller obtaining cleaning products. Based on this and his prior review, Mr. Petty concluded Jefferson: 1) supplied chemicals associated with BOOP to the school; 2) did not install or insure that adequate ventilation was present ; 3) did not provide adequate training on the hazards of the products; and 4) did not provide MSDS sheets for the products distributed to and at the school.[5] He also determined from the data developed during testing that the delivery or exposure mechanism was aerosolization and noted that particles of 10-20 microns in size were created that could be inhaled and particles of 5 microns in size were created that could be inhaled and reach the respirable areas of the lungs. The smaller particles were also capable of staying in the air the longest increasing the exposure and possibility of inhalation.

With respect to these preliminary conclusions, Mr. Petty examined the school where Plaintiff worked to identify and compare the ventilation rates using room volumes and ventilation flow rates. He then compared the flow rates determined for the rooms and spaces tested to the codes and standards he asserts are applicable: West Virginia Title 126, Series 172 (Handbook on Planning

[5]Plaintiff's Trial Exhibit 258-259; Daubert Exhibit 15, pp. 1069-1070.

School Facilities - 6200), Chapter 11 (Building Envelope/MEP/Indoor Environmental Systems and Technology); West Virginia Title 126, Series 174 (Investigating Indoor Air Quality Complaints) and ASHRAE 62-2001 (American Society of Heating, Refrigeration and Air Conditioning Engineer's Ventilation for Acceptable Indoor Air Quality Standard-2001 Version).[6] His examinations took place prior to the issuance of his April 25, 2006, supplemental report and prior to his May 23, 2006, supplemental report. As a result of the first visit, he concluded that the school did not have "adequate ventilation" for a particularized need under the "ASHRAE" standard.

On May 16, 2006, Mr. Petty reported on his review of the S.C. Johnson 2001 studies with respect to Virex and Blue Chip products containing ADBAC and DDAC and reliance thereon by Dr. Michael J. Wernke. He opined: 1) "[t]he mechanism for Ms. Kitzmiller's exposure is not represented in the cited report and referenced materials"; 2) "[t]he studies cited appear to have several inconsistencies" and 3) "[t]he studies cited provide materials which support our aerosol exposure mechanism." [7]

It was during this visit to the school where Ms. Kitzmiller worked that he found 0 to .4 air exchanges per hour in closed spaces instead of the normal or 4 to 10 air exchanges per hour. He found 23 or 24 spaces checked did not have normal ventilation within the recognized standard. Using his experience, particularly his experience in diesel air contamination, he concluded that "the exposure mechanism for Ms. Kitzmiller was exposure to aerosol particulate containing ADBAC while spraying products such as Blue-Skies II. In his December 29, 2005, report, he states the

[6]Petty serves as a voting member of ASHRAE TC 8.s and is a corresponding member of ASHRAE TC 3.5; has been a guest speaker at ASHRAE/AIHA and legal association functions.

[7]Plaintiff's Trial Exhibit 354, Daubert Exhibit 17, pp. 2262-2263.

product she reportedly used the most (2to 3 hours per day) was Blue Skies II. The exposure was enhanced by the lack of adequate ventilation in the school noted by the district and in our work on ventilation rates in various locations within the school (see my April 12, 2006 report). This exposure mechanism is consistent with the US EPA's concerns in their labeling recommendations . . . where they note: 'May be fatal if inhaled. Do not breath spray mist."'[8]

Mr. Petty revisited the Maysville Elementary School on May 16, 2006, to inspect the east and west boys' and girls' bathrooms, women's faculty bathroom, library bathroom, preschool bathroom, and basement media room to determine if each had adequate ventilation under the ASHRAE air quality standard adopted by West Virginia in West Virginia Code 18-9E-3. In his May 23, 2006, report, he concludes and is prepared to opine: 1) "[i]n general, the ventilation was not adequate as measured and compared with codes and standards and industry rules of thumb" and 2) "[g]iven the lack of ventilation, the locations where the cleaning chemicals were used do not meet the intent of good ventilation industrial hygiene practices."[9]

Based on the a review of Mr. Petty's testimony, his reports and supporting documentation for those reports, I conclude Mr. Petty is a witness qualified as an expert by knowledge, skill, experience, training, or education and may testify thereto in the form of an opinion or otherwise as to general causation opinions, but not specific causation opinions. In doing so, I find that the testimony he has to offer on the compounds found in Bath Mate and Blue Skies II; on the ventilation studies he performed on the various rooms in the Maysville Elementary School and on the ASHRAE standards; and on the S.C. Johnson studies is "scientific, technical, or other specialized knowledge"

[8]Plaintiff's Trial Exhibit 354, Daubert Exhibit 17, p. 2263.

[9]Plaintiff's Trial Exhibit 427, Daubert Exhibit 18, p. 2336.

which "will assist the trier of fact to understand the evidence or to determine a fact in issue." I further find his "testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and(3) the witness has applied the principles and methods reliably to the facts of the case." Oglesby v. General Motors Corp., *supra.*

With respect to each of Defendant's stated objections, using the flexible approach of Kumho, supra, I find:

1) the contention that Mr. Petty "failed to apply and follow the appropriate methodology in arriving at his opinions, rendering the same unreliable" is inconsistent with the facts presented. Mr. Petty may not have used the methodology Defendant wanted him to use, but there is no basis for the Court to conclude that the methodology he did use was flawed or "junk science."

2) the contention that "Petty's opinions as to Mrs. Kitzmiller's medical condition are proffered in an area wherein Petty is admittedly, 'not an expert' and are therefore, inherently unreliable" is rendered moot by the Court's determination that his testimony be limited to general causation including but not limited to: 1) inadequacy of ventilation in the rooms in the school where cleaning products were dispensed and used by Plaintiff as shown by his tests and physical examinations; 2) aerosolization in combination with inadequate ventilation increases the risk of exposure of Plaintiff to the chemicals she was using in her job; and 3) MSDS's warned that exposure to chemicals or compounds (benzalkonium compounds) may result in respiratory irritation and/or death;

3) the contention that "Petty's opinions as to improper ventilation are propounded upon

inappropriate methodology and are, therefore, unreliable" is inconsistent with the facts presented and the methods he used. TFWS v. Schaefer, supra; and

4) the contention that "Petty's ventilation opinions are untimely" is now rendered moot by the extensive depositions and Daubert hearing testimony. Defendant has had full discovery of Mr. Petty's opinions and his methods of arriving at those opinions through reports, supplemental reports and testimony.

For the reasons herein stated I **RECOMMEND** that Defendant's DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF STEPHEN E. PETTY, P.E., C.I.H. (Docket Entry 206) be **DENIED EXCEPT** Mr. Petty be precluded from testifying that Plaintiff's alleged BOOP was caused by work-related exposure to benzalkonium compounds contained in Bath Mate and Blue Skies II (specific causation). He should not be precluded from offering the opinions he specifically set forth in his reports and to general causation.

DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF MICHAEL J. WERNKE (Docket Entry 211)

Plaintiff seeks to exclude the proposed trial testimony of Dr. Michael J. Wernke (Dr. Wernke), asserting his testimony and expert opinions are not reliable and do not fit the overwhelming medical evidence diagnosing Plaintiff with BOOP.

Dr. Wernke, a toxicologist and pharmacologist, was retained by the Defendant and produced two reports dated February 8 and May 8, 2006. Based on analysis of the known facts relating to Plaintiff's case, using the Hill criteria[10], he found 1) Plaintiff's lack of reported symptoms of

[10]Hill criteria: 1) complete exposure pathway; 2) literature pertaining to causation; 3) evidence of dose; 4) temporal sequence; 5) other causes; and 6) known plausible biological mechanisms.

exposure for a period of time prior to the onset of disease, 2) the tests performed by the Butcher Company, 3) the existence of one case study which he found to be factually different from Plaintiff's case, 4) Plaintiff's initial treating physician's diagnosis of infectious pneumonia, supports his conclusion as a toxicologist that Plaintiff was not exposed to any dose of benzalkonium compounds, either through spraying (aerosolization) or pouring, which could have caused her BOOP.

Dr. Wernke's opinion testimony is limited to the method he used as a toxicologist to rule out one of the possible causes of BOOP. He accepted Plaintiff has BOOP. He simply stated her BOOP did not come from workplace exposure to cleaning fluids containing benzalkonium compounds. He performed tests spraying thirty-two ounces of undiluted product in a 382 square foot room and compared the air before and after the spraying. He spilled five gallons of the product in the same 382 square foot room and compared the air before and after spraying. From these tests he concluded there was insufficient aerosolization to reach industrial exposure levels where a respirator would be required or levels that could cause harm. The studies he performed were consistent with the procedures approved by the EPA and NIOSH. He accepted the fact that Ms. Kitzmiller worked in the school and used the subject cleaning products for a period of time prior to October, 2002, without any immediate symptoms and concludes that is evidence of a lack of a temporal connection between the alleged use and exposure to the chemicals and the onset of symptoms. He accepted that her early treating physician diagnosed her pneumonia to have been caused by some sort of infection, as additional evidence supporting his conclusion that her BOOP was not caused by exposure to the cleaning chemicals she used at work. He found only one case report in the literature linking exposure to benzalkonium compounds to BOOP. That was the Italian report. Because the reaction to the spilled compound was immediate in the Italian report, he concluded it was different enough

from the Kitzmiller case to not be reliable. However, he did accept it was sufficient to generate a hypothesis to be proved or disproved by other tests and information.

Plaintiff's challenges to the opinions and testimony of Dr. Wernke, claiming they do not "fit" the "relevant exposure evidence, school ventilation evidence, MSDS warnings not to use the cleaning chemical product without adequate ventilation and the harm that can occur from inhalation of the product, the evidence of fumes and aaerosolization, the thorough clinical assessment by differential diagnosis and tests including multiple confirming biopsies, to the scientific literature and to the analysis performed by Mr. Petty of settling velocities which show Linda's significant exposure to the aerosolized benzalkonium compounds and most of all to the overwhelming medical diagnostic opinions." These challenges are proper grist for the cross-examination mill, but hardly a basis for this gatekeeper to take away from the trier of fact the method used by Defendant's designated expert to reach his conclusion that Plaintiff's BOOP was not caused from exposure to Defendant's cleaning products. Westberry v. Gummi, supra.

Based on my review of the testimony of Dr. Wernke, his opinions and his methods, I find his "testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Oglesby v. General Motors Corp., supra. I cannot conclude that the expert scientific testimony of Dr. Wernke as offered will not assist the trier of fact to understand or determine a fact in issue (dose and exposure). Daubert, supra.

For the reasons herein stated I **RECOMMEND** that PLAINTIFF'S DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF **MICHAEL J. WERNKE** (**Docket Entry 211)** be **DENIED**.

DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF DR. RICHARD CATLETT ON THE ISSUES OF CAUSATION (Docket Entry 204)

Defendant seeks exclusion of the opinion testimony of Dr. Richard Catlett (Dr. Catlett) on issues of causation, general and specific, because: 1) he was not disclosed as an expert witness and 2) he failed to apply and follow the appropriate methodology in arriving at his opinions, making them nothing more than his own *ipse dixit*.

Dr. Catlett is one of seven physicians in the Winchester Pulmonary & Internal Medicine Practice serving patients in Virginia, West Virginia and Pennsylvania. At one time, Dr. Catlett was board certified in both internal medicine and pulmonary medicine. However, he has not recently taken the examinations to keep his board certification in pulmonary medicine current and has let it lapse.

Dr. Catlett has previously diagnosed and treated cases of BOOP. He testified during the Daubert hearing that he had seen between thirty and fifty BOOP cases over the course of his career. Currently, and over the recent past, Dr. Catlett testified he treats and has treated between one and three cases of BOOP per year. He describes BOOP as a special type of pneumonia. It is non-infectious because it is not caused by bacteria. It manifests itself as an inflamation of the bronchioles- distal airways such that oxygen does not effectively get to the aveoli where the oxygen exchange between air and blood takes place. BOOP is characterized by a dry "hacky" non-productive cough.

Dr. Catlett first saw Plaintiff in a clinical setting in January, 2003. She had already been diagnosed with BOOP by another treating physician. Dr. Catlett examined Plaintiff and reviewed the records from Drs. Schmidt and Kunkle as forwarded to him by the referring physician, Dr.

Kunkle. The records reviewed consisted of: a trans-bronchial biopsy report dated December 19, 2002, and x-rays from Mountainview Hospital.

According to Dr. Catlett, his initial or primary focus was on treatment, not etiology. However, he did note a history of symptom initiation in October, 2002.

Based on the tests, it was Dr. Catlett's opinion that when Plaintiff was removed from prednisone therapy, her symptoms increased. Those same symptoms reduced when she was receiving the prednisone therapy.

He concurred in the Drs. Schmidt and Kunkles' diagnoses of BOOP and continued the prednisone steroid regimen initiated by them.

On March 25, 2003, Plaintiff turned her complete care over to Dr. Catlett.

On March 25, 2003, Dr. Catlett orderd a CT scan of Plaintiff's lungs. The scan reflected abnormalities in both lungs. A repeat bronchoscopy and other tests ruled out: fungus, TB, sarcoidosis[11] and other lung diseases as the cause of Plaintiff's BOOP. Plaintiff's pulmonary functions studies were relatively normal. Dr. Catlett explained it is not unusual to have BOOP and normal pulmonary function studies. He opines the normal result in Plaintiff may have been the result of her prednisone steroid therapy.

Dr. Catlett dismissed the use of an open lung biopsy in Plaintiff's case because the risks inherent in the test would not be justified. He felt the results would not likely change the treatment regimen.

Between 2004 and the date of the Daubert hearing testimony, Dr. Catlett became interested

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[11]"A chronic, progressive, systemic granulomatous reticulosis of unknown etiology, characterized by hard tubercles (q.v.) In almost any organ or tissue including the skin, lungs, ..." Dorland's Illustrated Medical Dictionary, 30th Edition.

in the cause of Plaintiff's BOOP. His notes of April 21, 2004, reflected Plaintiff's insistence that her body had changed in October, 2002, and that her condition was associated with exposure to cleaning solutions at work.[12] Earlier notes indicate the following:

October 17, 2003 "In spite of this, Ms. Kitzmiller does find that she has heightened sensitivity to nonspecific bronchial irritants. For example, when she is exposed to fumes from hairdressing salon, she went into bronchospasm and felt her lungs to be quite tight. When she has been exposed to some construction dust and fumes from new house construction, she has had difficulty breathing. If she is exposed to any fumes from Clorox or strong cleaning solutions, breathing seems to tighten up as well." Exhibit 40. Trial Exhibit 1041.

October 17, 2003 "Heightened nonspecific bronchial irritability, precluding continued employment as a custodian." Exhibit 40. Trial Exhibit 1042.

April 21, 2004 "Ms Kitzmiller still feels symptoms of shortness of breath when exposed to perfumes and at times with change in weather. At times she is worse when exposed to cigarette smoke." Exhibit 40. Trial Exhibit 1044.

June 15, 2005 "Ms. Kitzmiller did visit the school where she had done custodial work in the company of her disability lawyer. When re-exposed to fumes within a certain area of the school, there was a flare in asthmatic symptomatology." Exhibit 40. Trial Exhibit 1047.

October 28, 2005 "Since then [evaluation of 6/15/05], Ms. Kitzmiller did go to the school where she had worked previously, where her granddaughter is enrolled. Upon entry into the school, there was marked flare in respiratory symptoms with cough and shortness of breath. Evidently, the superintendent of schools was there, saw the episode, and advised that Ms. Kitzmiller vacate the premises for Ms. Kitzmiller's own health. Ms. Kitzmiller had been doing reasonably well subsequently, up until three weeks ago, when she was exposed to possible virus and/or strong fumes, while at church. Since then, there has been persistent cough, achiness in the chest associated with coughing and some intermittent shortness of breath. It is noted in the report [worker's compensation IME report performed at Department of Occupational Medicine, WVU dated October 5, 2005] that Ms. Kitzmiller

[12] "I do find it interesting that Ms. Kitzmiller's body seems to have undergone a fundamental change after her bronchiolitis in October 2002, which seemed to be associated with exposure to cleaning solutions at work." Ex 40, Trial Exhibit 1044.

has a history since her initial exposure of adverse reactions to nonspecific bronchial irritants, specially including deodorants [sic], flowers, perfumes, cigarette smoke, gasoline, cleaning agents, burlap, and candles." Exhibit 40. Trial Exhibit 2218.

May 19, 2006 "Ms. Kitzmiller remains adamant that she did not have any lung disease until she had exposure to cleaning materials in a closed environment at her previous work with the school system." Exhibit 40. Trial Exhibit 2221.

Dr. Catlett testified that his interest in the cause of Ms. Kitzmiller's BOOP was piqued by her reported reactions to cleaning fluids while under his care. He further testified Ms. Kitzmiller brought him some MSDS's sometime in 2004, and they appeared to him to be standard cleaning agents. Nothing of note stood out at that time. He looked at the agents allegedly involved over the period of the last six months and determined that the products, Bath Mate and Blue Skies, contain anti bacterials which kill cells and have caused coreal irritation and cause the body to attack itself. Approximately three days prior to his Daubert hearing testimony, Dr. Catlett found the Italian study in the Journal of Occupational Health, a single case report linking benzalkonium compounds to BOOP.

Dr. Catlett has done no studies, double blind or otherwise, to connect exposure to benzalkonium compounds and the onset of BOOP in humans. He did not visit the school and conduct or observe any tests to determine exposure or dose or improper ventilation. In the beginning of his treatment of Ms. Kitzmiller, he did not determine the alleged cause of the BOOP and did not deem cause important in formulating the diagnosis of BOOP or a treatment plan for BOOP. His primary basis for concluding exposure in this case is the historical information he was given by his patient, Ms. Kitzmiller, and her statements and insistence of the temporal relationship between her using the cleaning chemicals at school in October, 2002, and the onset of her symptoms. His basis for concluding that exposure to benzalkonium compounds caused Ms. Kitzmiller's BOOP was

differential diagnosis. He ruled out other causes of Plaintiff's BOOP, such as fungus, TB, Sarcoidosis and other lung diseases by repeat bronchoscopy, the ACE level test and other tests previously noted, and the clinical findings and tests of other treating physicians, and the historical course and results achieved from the prednisone treatment protocol.

He considered and formed an opinion of temporal proximity based on the history of symptom onset given him by his patient and the MSDS for Bath Mate and Blue Skies reflecting some presence of benzalkonium compounds and the one Italian case report.

He concludes and is prepared to testify, if permitted, that the general causation and specific causation of Plaintiff's BOOP was the exposure to the cleaning chemicals in the school where she worked. He supports his opinion that the cleaning chemicals Ms. Kitzmiller used were the cause of her BOOP by his understanding that the MSDS notes lung irritation as one result of exposure and his knowledge that the compounds in the cleaning solutions contain anti-bacterials that kill cells and have been known to cause corneal irritation and cause the body to attack itself.

With respect to Dr. Catlett's opinions, there has not been any testing of his theory. His opinions have not withstood peer review and publication. There is no known or potential rate of error with respect to his opinions. No standards exist for the application of his theory. There has been no showing that his theory has been generally accepted by the relevant scientific community. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U. S. 579 (1993). However, these failures are not dispositive.

Plaintiff relies heavily on the line of cases permitting a treating physician who arrived at his opinions using the differential diagnosis method, a method well established and long approved in medicine, to express those opinions.

The general rule is that clinical, treating physicians using reliable differential diagnosis techniques should be permitted to testify within the field of the expertise under the flexible approach provided by Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999). Kumho moved away from blind adherence to the four factors set forth in Daubert, instead requiring that the "particular circumstances" of the "particular case" at issue be identified to determine if the case required scientific expertise or more personal knowledge and / or experience; to determine what, if any, Daubert factors were applicable in the process of determining the reliability of the experts opinion.

Heller v. Shaw Industries, Inc., 167 F.3d 146 (3rd Cir. 1999) (pre Kumho). Plaintiff claimed his respiratory problems were caused by volatile organic compounds emitted by carpet. The district court held an *in limine* hearing and excluded plaintiff's industrial hygienist and medical witness. The Third Circuit held that the trial court properly excluded the industrial hygienist but erred in excluding the medical expert. In doing so the Court held:

> Assuming that Dr. Papano conducted a thorough differential diagnosis...and had thereby ruled out other possible causes of Heller's illness, and assuming that he had relied on a valid and strong temporal relationship between the installation of the carpet and Heller's problems ... we do not believe that this would be an insufficiently valid methodology for his reliably concluding that the carpet caused Heller's problems.
>
> [W]e do not believe that Daubert ... require[s] a physician to rely on definitive published studies before concluding that exposure to a particular object or chemical was the most likely cause of a plaintiff's illness. Both a differential diagnosis and a temporal analysis, properly performed, would generally meet the requirements of Daubert.

In the earlier case of In re Paoli R.R. Yard P.C.B. Litigation, 35 F.3d 717 (3rd Cir. 1994; cert denied, 513 U.S. 1190 (1995), the Third Circuit held a medical opinion based upon a reliable differential diagnosis is sufficient to satisfy a Rule 702 inquiry and that the performance of physical examinations, taking of medical histories and employment of reliable lab tests all provide significant

evidence of reliable differential diagnosis and will allow a doctor who employs them to testify to novel conclusions.

The Second Circuit allowed testimony of a medical doctor as to the possible cause of a throat ailment of a worker who had been exposed to glue fumes in McCullock v. H.B. Fuller Co., 61 F.3d 1038 (2nd Cir. 1998). The Court described differential etiology as an analysis requiring the listing of possible causes and the elimination of all but one of those causes.

The Ninth Circuit reversed the trial court for abuse of discretion in excluding an experts opinion on causation that was based on a reliable differential diagnosis. The Court concluded that the medical expert's opinion that collagen caused autoimmune disorders, such as lupus; that plaintiff suffered from lupus after collagen injections; and that such opinions reflected scientific knowledge in spite of the lack of epidemiological or animal studies and were admissible particularly when they were the result of medical studies, observation of the Plaintiff's injuries, medical history and lab tests. Kennedy v. Collagen Corp., 161 F.3d 1226 (9th Cir. 1998) cert. denied, 526 U.S. 1099 (1999).

Of most significance to the undersigned is the decision of the Fourth Circuit in Westberry v. Gislaved Gummi AB, 178 F.3d 1257 (4th Cir. 1999). Westberry was employed by a company making windows and skylights. The defendant manufactured the rubber gaskets used in the process of making the windows and skylights. It was Westberry's job to handle and cut the gaskets as part of the process. He was not provided with protective gear. The talc used in the process was thick and covered Westberry, his clothes and his work area. Within a short time of commencing this job, Westberry developed severe sinus problems which ultimately required surgery. Using the differential diagnoses approach supported in part by the temporal relationship between Westberry's exposure to talc and his development of sinus problems, Westberry's treating physician offered the

primary evidence of causation. The Fourth Circuit rejected defendant's argument that the physician's testimony was inadmissible because it was not based on reliable scientific methodology such as epidemiological studies, animal studies, laboratory data, or tissue sampling. The Court held:

> Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated .... A reliable differential diagnosis typically, though not invariably, is performed after physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely cause.

Similar to the instant case, the Fourth Circuit, in addressing the Westberry physician's lack of an accurate assessment of the exact levels of talc exposure suffered by Westberry and the temporal proximity relied on by the physician, noted that there was testimonial evidence to permit a fact finder to determine that there was a substantial exposure to the talc which the Material Safety Data Sheet (MSDS) defined as a mucous membrane irritant. It also noted that "depending on the circumstances, a temporal relationship between exposure to a substance and the onset of da disease or a worsening of symptoms can provide compelling evidence of causation." It went on to suggest that alternative causes suggested by the Defendant affected the weight but not the admissibility of the expert's testimony.

In Benedi v. McNeil - P.O.C., Inc. , 66 F.3d 1378 (4th Cir. 1995), the Court held testimony of the treating physicians relative to the cause of plaintiff's liver failure was admissible and not unreliable if based on history, exam, lab data and literature, even if it lacked epidemiological data as support primarily because of the medical community's daily use of the methodology.

Defendant argues admission of Dr. Catlett's opinion testimony on general and specific causation amounts to nothing more than lending the credibility of a very experienced pulmonologist to the historical complaints of his patient, Linda Kitzmiller. While "'[t]he trial court's gatekeeping function requires more than simply 'taking the expert's word for it' and [t]he more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable" (Advisory Committee Note to Rule 702 (internal citations and quotations omitted)), Defendant has not shown that Dr. Catlett's differential diagnosis approach to his causation opinions is unreliable such that the proffered opinions should be ruled inadmissible.

For the foregoing reasons, under the facts of this case, I find that the opinions on causation propounded by Dr. Catlett are founded on: 1) a differential diagnosis by a treating physician who is also a trained and experienced pulmonologist; 2) a strong temporal relationship between the use of cleaning chemicals by Plaintiff in the school and the onset of symptoms and disease all as consistently reported to the treating physicians by the Plaintiff as part of her medical history; 3) his ability to use his technical education and experience to connect known and reported potential deleterious effects of some of the compounds in the cleaning solutions used by Plaintiff on human cell life, including, but not limited to, lung tissues; 4) the ability to read and understand the connection between one case report and the exposure of Plaintiff to cleaning materials containing the same or similar compounds; and 5) the ability to use his technical education and experience to understand the connection between the warnings contained in the MSDS's supplied for the cleaning supplies used by Plaintiff and the specific symptoms and illness suffered by Plaintiff after her proximal use of those cleaning supplies.

With respect to Defendant's claim that Dr. Catlett's opinions should be rejected because no

Rule 26 (a)(2)(B) report was filed, following the logic in Sullivan v. Glocke, Inc., 175 F.R.D. 497, 501 (D. Md. 1997) and a host of other cases as well as the commentaries to the Rule,[13] I conclude the source of facts which formed the basis for Dr. Catlett's opinions were, in large measure, derived from information learned by him and others during the treatment of Ms. Kitzmiller and were not the result of information supplied by an attorney involved in litigating the case. In such a case, no report is required as a pre-requisite to testimony. In addition, Defendant has had the opportunity to depose Dr. Catlett and to cross examine him extensively during his Daubert hearing testimony. That renders the whole purpose behind the report required under Rule 26 (a)(2)(B) moot.

Accordingly, I **RECOMMEND** that Defendant's DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF DR. RICHARD CATLETT ON THE ISSUES OF CAUSATION (Docket Entry 204) be **DENIED.**

DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF DR. SAMUEL VINCENT SPAGNOLA (Docket Entry 202)

Samuel Vincent Spagnola ("Dr. Spagnola") is a physician board certified in Internal Medicine, Pulmonary Medicine and Critical Care Medicine. In addition to the usual credentials, Dr. Spagnola was part of the team who treated President Ronald Reagan when he was shot during John Hinkley's assassination attempt; consulted in the care of Pope John Paul II and assisted in the care

[13]Sprague v. Liberty Mut. Inc. Co. 177 F.R.D. 78, 81 (D. N.H. 1998); Zurba v. United States, 202 F.R.D. 590, 592 (N.D. Ill. 2001); Hall v. Sykes, 164 F.R.D. 46, 48 (E.D. Va. 1995) and Salas v. United States, 165 F.R. D. 31, 33 (W.D.N.Y. 1995). See also commentary to 1993 Amendments to Rule 26(a)(2): "The requirement of a written report in paragraph (2)(B), however, applies only to those experts who are retained or specifically employed to provide such testimony in the case or whose duties as an employee of a party regularly involve the giving of such testimony. A treating physician, for example, can be deposed or called to testify at trial without any requirement for a written report. ..."

of President George H.W. Bush. In addition he has trained approximately 110 pulmonary medicine specialists. Dr. Spagnola is retained by Defendant to offer expert opinions concerning the diagnosis and cause of lung problems experienced by Plaintiff and which are a subject of this litigation.

Dr. Spagnola did not examine Plaintiff. He did not have any tests performed on the Plaintiff. His opinions result from his review of Ms. Kitzmiller's medical records through June, 2005. He described his method of evaluation as the differential diagnosis method.

Based on his limited review, he opined that: Plaintiff does not suffer from BOOP; her ear pain, sore throat and abnormal chest x-rays (increased density in the lower lung) is indicative of an infectious disease process; that the infections developed into infectious organizing pneumonia or cryptogenic pneumonia, but that she was recovering; Plaintiff's organizing pneumonia was exacerbated by GERD which was caused by a large hyiatal hernia and aspiration of stomach fluids and acid into her esophagus and lungs. He further opined BOOP was no longer a term favored by the American Thorasic Society.

"Scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence (results of early tests performed by Drs. Kunkle and Schmidt, Plaintiffs complaints and history) or to determine" whether Ms. Kitzmiller had BOOP. Through June, 2005, Dr. Spagnola had the same information Drs. Kunkle, Schmidt and Catlett had and used in reaching their conclusions. It stands to reason, if the test results and symptoms (facts or data) were adequate for Drs. Kunkle and Schmidt to formulate a diagnosis and plan of treatment of BOOP, surely those same facts and data are adequate for another qualified physician to use to formulate a different diagnosis. Other than not looking at data after June, 2005, there is nothing to show that Dr. Spagnola did not reliably apply the principles and methods of a differential diagnosis to the facts

of this case. I cannot say that Dr. Spagnola's opinions are unreliable. Many physicians offer diagnosis and treatment of patients based on the records as opposed to seeing the patient in a clinical setting. Their opinions, like those of Dr. Spagnola, are subject to the challenges of rigorous cross examination and ultimately jury consideration. In short, there are many situation such as this where qualified experts look at the same set of facts and reach differing conclusions. That is not unusual. These do not require the exercise of difficult gate keeping scrutiny on my part. It is not my duty to weigh and decide the evidence presented by the differing opinions of these qualified experts.

For the reasons herein stated I **RECOMMEND** Plaintiff's DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF DR. SAMUEL VINCENT SPAGNOLA (Docket Entry 202) be **DENIED.**

DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF DR. DOMINICK GAZIANO (Docket Entry 205)

Dr. Dominick Gaziano ("Dr. Gaziano") is a Pulmonary, Critical Care and Internal Medicine specialist Plaintiff's counsel knew and requested conduct and independent medical evaluation of Plaintiff. Dr. Gaziano saw Plaintiff in a clinical setting March 17, 2005. He conducted his own pulmonary function studies, did his own x-rays, took a history from the Plaintiff, and examined her head, neck, chest and heart. Plaintiff's physical exam was normal. The pulmonary functions studies were all normal ("spirometry was normal, lung volumes were normal, diffusing capacity for carbon monoxide was normal.) X-rays "showed essentially cleared lung fields, healed rib fracture on the left, calcified granulomata, and slight plate-like atelectasis in the bases. Plaintiff's Trial Exhibit 1138, Daubert Exhibit 46.

Dr. Gaziano reviewed materials provided by Plaintiff and her lawyer:

a. 2/8/05 letter from Dr. Kunkel stating Plaintiff had "severe BOOP as the result of

exposure to chemicals";

b. 12/14/04 pulmonary function test from Western Maryland Health Center;

c. 10/27/04 high resolution CT scan of the chest;

d. 3/26/03 CT scan from Winchester Medical Center;

e. 11/26/02 high resolution CT scan;

f. Photo of plastic bottles of solution and a mixing apparatus with MSDS information showing with respect to Blue Skies disinfectant cleaner "Inhalation of the mist may cause irritation" and "Solution #16 revealed chemical substances that may produce respiratory problems if inhaled" and "Item #22, known as Speed Ball, also contained substances that could irritate the mucous membranes and respiratory system";

g. Unsigned and undated statement of Mrs. Kitzmiller explaining "her exposures and medical condition as the result of these exposures";

h. 11/20/03 report of Dr. Kunkel;

i. Note of Dr. Kunkle;

j. 10/17/03 report of Dr. Kunkel;

k. 1/24/03 report of Dr. Catlett;

l. 11/06/02 Grant County Hospital records;

m. 10/24/02 Chest x-ray and follow up x-rays;

n. 12/19/02 transbronchial lung biopsy;

o. 10/25/04 report of Dr christopher Martin;

p. Journal of Occupational Health 2003 case report "a case of syndrome associated with heavy exposure to floor cleaning solution";

q. Winchester Medical Center reports and x-ray of 6/27/03;

r. Myeloperoxidase antibody - negative and CANCA levels done 6/25/03;

s. Lung biopsy 5/08/03 showing findings consistent with BOOP;

t. Dr Catlett report dated 1/23/03;

u. Dr. Catlett evaluation and report dated 3/25/03;

v. Normal blood gas study dated 3/26/03;

w. Pulmonary function test reports dated 3/26/03;

x. Handwritten treatment notes of Dr. Kunkel;

y. X-ray of 11/19/02;

z. Emergency room note of 11/19/02;

aa. 12/19/02 transbronchial biopsy;

bb. Dr. John E. Welsh dated 10/02/03.

Based on the foregoing, Dr. Gaziano opined on March 17, 2005, testified at the Daubert hearing and proposes to testify at trial: "It is my opinion, to a reasonable degree of medical certainty, that Mrs. Kitzmiller developed bronchiolitis obliterans and organizing pneumonia as the result of her inhalation of chemical substances in the work place. She continues to have sensitivity to various agents, however, has not demonstrated any bronchospastic or asthmatic findings on pulmonary function tests or clinical evaluation. I believe this represents a non-specific response to noxious agents. She is on continued steroid medication, which is somewhat unusual for this disorder. She has considerable musculoskeletal abnormalities and particularly complains of significant symptoms in both forearms. This may represent a compression neuropathy associated with the use of prolonged steroid administration. This area is out of my medical specialty and perhaps neurological

assessment and EMG may clarify this component of her illness."

Dr. Gaziano did not study how much of a dose of the alleged culprit substance Ms. Kitzmiller had to receive in order to develop BOOP. During his Daubert hearing testimony, he concluded she had BOOP and based on his differential diagnosis, he opines she got it from using the cleaning supplies at work and, therefore, had some dose sufficient to cause BOOP. Dr. Gaziano did not consider any ventilation studies or data. Dr. Gaziano did not review Dr. Schmidt's records reflecting his opinion that Ms. Kitzmiller's pneumonia was infectious in nature. He did not consider any of the Butcher studies.

Generally, FRE 702 requires two elements be met before expert testimony is admissible:

1) reliability and

2) admission will assist the trier of the fact understand the facts. Daubert, *supra* at 592.

The reliability element may be met if the:

1) proposed witness is qualified as an expert on the issues in dispute. Cooper v. Lab. Corp. of Am. Holdings, Inc., 150 F.3d, 376, 380-381 (4th Cir. 1998): "Expert witness must have either knowledge, skill, experience, training, or education; these are disjunctive, and an expert can qualify to testify on any one of the grounds." I find that Dr. Gaziano is qualified as an expert in Pulmonology.

2) testimony is based on sufficient facts or data. Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199, n. 1, 200-2002 (4th Cir. 2001): "A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods."

3) testimony is "the product of reliable principles and methods."

4) expert "applied the principles and methods reliably to the facts of the case." Cooper v. Smith & Nephew, Inc., *supra* at 200-2002.

With respect to the last three prongs of the reliability element, it is apparent from Dr.

Gaziano's deposition and Daubert hearing testimony that he did not know the identities of products Ms. Kitzmiller used at home or at work other than Bath Mate and Blue Skies; did not have particularized knowledge of how Ms. Kitzmiller used the suspect products, much less the other products she may have used in cleaning at work or home; did not consider or have knowledge with respect to the Butcher Company inhalation studies with respect to benzalkonium compounds present in Bath Mate and Blue Skies; did not know with any particularity what level of dose of the compounds Ms. Kitzmiller had been exposed to during her work; did not know what length of time she may have been exposed to any dosage of the compounds while at work; knew of the dispensing station but had no particulars on its operation; never authored an article on BOOP or the causes of BOOP; had never previously offered opinion testimony in BOOP cases; had only treated four or five cases of BOOP in his forty-plus-year medical career; had not authored any articles on BOOP; and was not able to explain the similarities, if any, between the one Italian case report and Ms. Kitzmiller's alleged exposure. Even more troubling is the fact that Dr. Gaziano acknowledges there are multiple causes of BOOP, but he did not endeavor to eliminate or explain why causes such as epigastric aspiration infectious process like that diagnosed by Dr. Schmidt at the outset could be ruled out of the causation equation.

Accordingly, I find that Dr. Gaziano's opinions are not based on sufficient facts and are not the result of the application of the otherwise reliable differential diagnosis method followed by treating physicians.[14]

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[14] Dr. Gaziano is not a treating physician. He is not entitled to the deference the Court grants to treating physicians who seek to express opinions developed through the process of their differential diagnosis and treatment of their patient. To the extent he performed a differential diagnosis, it is incomplete and flawed. Admission of Dr. Gaziano's opinion testimony on causation amounts to

In addition, Dr. Gaziano adds nothing that is not already testified to by the other doctors and experts appearing for the Plaintiff. He is cumulative of the opinions and testimony of others. While Plaintiff may be entitled to get her version of her case to the jury by one or a combination of experts, she is not entitled to cumulative testimony.

Dr. Gaziano's opinions are based on the opinions and conclusions of others including Dr. Kunkel. I have previously ruled and limited Dr. Kunkel's testimony to his treatment of Ms. Kitzmiller, precluding him from offering opinions relative to causation. I find that Dr. Gaziano is not in a position to offer opinion testimony on causation for the reasons previously set forth.

Accordingly, it is my **RECOMMENDATION** that the DAUBERT MOTION TO

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nothing more than lending the credibility of a very experienced pulmonologist to the historical complaints of the Plaintiff. "In cases where medical expert's opinion based upon differential diagnosis failed to rule out every possible cause of plaintiff's illness, the alternative causes suggested by defendant normally affect the weight that jury should give expert's testimony and not admissibility of that testimony; however, differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.

If medical expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert's testimony.

Patient's medical expert's opinion which rejected patient's smoking as potential cause of patient's failed spinal fusion, and concluded that defective spinal fusion device was sole cause was unreliable, and thus expert's testimony was inadmissible for purpose of patient's action against manufacturer of fusion device alleging that device caused fusion failure; although medical expert read two articles indicating that smoking caused fusion failures, expert stated that he did not consider any other medical literature, and expert did not explain how he ruled out smoking and other potential causes of fusion failure.

Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert."

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199, n. 1, 200-2002 (4th Cir. 2001)

EXCLUDE THE TESTIMONY OF DR. DOMINICK GAZIANO (Docket Entry 205) be **GRANTED.**

DAUBERT MOTION TO EXCLUDE OPINION TESTIMONY OF DR. ALLAN KUNKLE ON ISSUE OF CAUSATION (Docket Entdry 207)

Dr. Kunkel was Ms. Kitzmiller's treating physician. According to his own testimony, he did not independently diagnose Ms. Kitzmiller to have BOOP. He adopted that diagnosis as made by other doctors who were specialists. He did not relate Ms. Kitzmiller's use of cleaning chemicals at work at the school to her BOOP. Again, he adopted the opinion of another. He was not aware of the chemicals Ms. Kitzmiller used to clean at school or what chemical compounds were contained in those chemicals. He was unfamiliar with any dose she may have received of any chemical associated with causing BOOP. He had never seen or been involved in the treatment of a case of BOOP before Ms. Kitzmiller's case.

Based on the above and more, consistent with a prior oral pronouncement, I now find Dr. Kunkel unqualified to render opinions with respect to the general and specific causation issues in the instant case.

Such finding does not preclude Dr. Kunkel from testifying with respect to tests and the results of tests he performed or had performed on Ms. Kitzmiller, the results of examinations her performed on Ms. Kitzmiller, the history he noted from Ms. Kitzmiller during his care and treatment of her; the symptoms and conditions he personally observed with respect to Ms. Kitzmiller during his care and treatment of her; the effects of the treatment or treatments on Ms. Kitzmiller during his care and treatment of her.

Accordingly, it is **RECOMMENDED** that Defendant's DAUBERT MOTION TO

EXCLUDE OPINION TESTIMONY OF DR. ALLAN KUNKLE ON ISSUE OF CAUSATION (Docket Entdry 207) be **GRANTED.**

Any party may, within ten (10) days after being served with a copy of this Report and Recommendation, file with the Clerk of the Court written objections identifying the portions of the Report and Recommendation to which objection is made, and the basis for such objection. A copy of such objections should also be submitted to the Honorable Robert E. Maxwell, United States District Judge. Failure to timely file objections to the Report and Recommendation set forth above will result in waiver of the right to appeal from a judgment of this Court based upon such Report and Recommendation. 28 U.S.C. § 636(b)(1); United States v. Schronce, 727 F.2d 91 (4th Cir. 1984), cert. denied, 467 U.S. 1208 (1984); Wright v. Collins, 766 F.2d 841 (4th Cir. 1985); Thomas v. Arn, 474 U.S. 140 (1985).

The Clerk of the Court is directed to send a copy of this Report and Recommendation to counsel of record.

Respectfully submitted this 15TH day of February, 2007.

/s *John S. Kaull*
JOHN S. KAULL
UNITED STATES MAGISTRATE JUDGE